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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA File No 618-OL. Abamectin. "AFFIRM Technical"
Product Chemistry. Accession Number 258707.
RCB No 1313.

FROM: Leung Cheng, Chemist *L. Cheng* 145928
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Andrew R. Rathman, Section Head
Residue Chemistry Branch
Hazard Evaluation Division (TS-769) *ARR*

TO: George LaRocca, PM #15
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Merck, Sharp & Dohme has requested the registration of "AFFIRM Technical", which contains abamectin [a mixture of 5-O-demethyl-avermectin A_{1a} (aka avermectin B_{1a}) and 5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)-avermectin A_{1a} (aka avermectin B_{1b})] as the active ingredient, to be used only for the formulation of fire ant bait products.

The accompanying Confidential Statement of Formula (CSF) lists "AFFIRM Technical" as containing 70% minimum abamectin, 5% maximum "related compounds" and 25% maximum "inerts". The CSF does not specify the purity of the abamectin used (however, see the next paragraph), nor does it identify those "related compounds" and the "inerts". Merck will need to furnish these data on the CSF.

Tab A3 of the submission (Product Identity and Disclosure of Ingredient for Abamectin Technical (MK-936) and AFFIRM Technical) discusses the minimum purity of the active ingredient and the ratio of B_{1a}:B_{1b}. These numbers are the same as those reported previously (PP4F3065, F. Boyd, memo of 9/13/84). The current manufacturing (fermentation) process has not been provided. Merck is required to supply this information, as well as on those impurities formed during this process, prior to registration.

Certain physical and chemical properties have been attached. Since inerts are intentionally added, "AFFIRM Technical" is considered a manufacturing-use product (MUP). Submitted value on the density is for the active ingredient and not for the MUP. The pH value needs to be furnished. We also need information on the storage

stability, explodability, miscibility, corrosiveness and viscosity on this MUP. Merck should check Pesticide Assessment Guidelines, Subdivision D for details.

Further, we require analysis on five or more representative batches of "AFFIRM Technical". Results should include both the active ingredient and the impurities.

Conclusions and Recommendation

1. "AFFIRM Technical" is a manufacturing-use product (MUP).
2. The registrant needs to supply identities of the "related compounds" and the "inerts".
3. Detailed information on the current manufacturing (fermentation) process as well as the resulting impurities should be furnished.
4. Certain physical or chemical properties are lacking. The registrant is required to supply information on the density, pH, storage stability, explodability, miscibility, corrosiveness and viscosity of "AFFIRM Technical".
5. Merck also needs to furnish results of the active ingredient and the impurities on analysis of five or more representative batches of this MUP. The registrant should check Pesticide Assessment Guidelines, Subdivision D for details.

We recommend that the registration of "AFFIRM Technical" be denied at this time.

cc:Circ, RF, SF, Cheng, Amended Use F, PMSD/ISB
RDI:ARRathman:11/1/85:RDSchmitt:11/1/85
TS-769:RCB:LCheng:CM#2:RM810:11/1/85:557-7484

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